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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:	Ann M. Maloney	) Confirm. No.:	1738
Serial No.:	10/657,011	) Art Unit:	1618
Filed:	September 5, 2003	) Examiner:	Blessing M. Fubara
For:	Opioid Sustained Release Formulation		
Docket No.:	10/041-2-C2		

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

July 1, 2005

RESPONSE

Sir:

This is in response to a communication from the Examiner in charge of the subject application, which communication was mailed on May 5, 2005. The communication mailed May 5th comprises a final rejection.

Reconsideration of the final rejection is respectfully requested.

The Examiner has withdrawn the rejection under 35 U.S.C. §112 and 35 U.S.C. §102. The Examiner has also withdrawn the rejection under 35 U.S.C. § 103 over Eichman in view of Chow. However, the Examiner is now rejecting claims 50 through 52 in the subject application under 35 U.S.C. §103 as being unpatentable over Chow. Claims 50 and 54 also stand rejected under 35 U.S.C. §103 as unpatentable over Chow in view of applicant's admitted prior art on the resins. The status of claim 53 was not addressed in the May 5th communication.

As stated by applicant, the use of a fine particle size resin where more than about 90% of the resin particles pass through a 325 mesh screen significantly improves the sustained release profile of oxycodone formulations. As noted by the applicant, biostudies of formulations made according to the claimed invention demonstrate that such formulations provide absorption equivalent to that obtained with oral oxycodone solutions with lower Cmax. (Specification at page 13). In a conventional tablet form (including the formulations taught by Chow), oxycodone, a highly water soluble compound, typically has a half-time of absorption of about 0.4

hours, a half-life of approximately 2 to 3 hours and a duration of action of approximately 3 to 4 hours. (Specification at page 14). In contrast, by using the teachings of the subject application, a controlled release formulation of oxycodone can be obtained, resulting in a peak plasma level of oxycodone obtained in vivo between five and six hours. (Specification at page 14). This is surprising and not obvious in view of Chow, either alone or combined with the known properties of resins identified by the applicant.

In view of the foregoing, it is respectfully submitted that the subject application is in condition for allowance, and such favorable action at an early date is earnestly solicited.

Respectfully submitted,

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on July 1, 2005.

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